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Food Safety And Inspection Service
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AUDIT REPORT FOR BRAZIL

JANUARY 9 THROUGH FEBRUARY 6, 2002

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Brazil's meat inspection system from January 9 through February 6, 2002. Thirteen of the 29 establishments certified to export meat to the United States were audited. Four of these were beef slaughter and boning establishments; four were beef slaughter, boning, and conducting processing operations; two establishments were conducting processing operations and the other one was producing beef extract and other dairy products.

The last audit of the Brazilian meat inspection system was conducted in July 2001. Nine establishments were audited. The auditor found significant problems in three establishments (SIF 458, SIF 504, and SIF 4507) that were then designated as marginal/re-review. Hazard Analysis and Critical Control Points (HACCP) systems implementation was deficient in eight of the nine establishments visited.

The major concerns from the previous audit were the following.

- The lack of periodic supervisory reviews of certified establishments.
- In eight establishments, the final review of all documentation associated with the production of the product prior to shipping was not done. (SIF 76, SIF 385, SIF 421, SIF 458, SIF 504, SIF 2023, SIF 2979, SIF 4507)
- In seven establishments, the critical limits that were set were not measurable. (SIF 76, SIF 226, SIF 421, SIF 458, SIF 2979, SIF3673, and SIF 4507)
- In two establishments, the HACCP plan did not adequately address the corrective actions to be followed in response to deviations from critical limits. (SIF 2023 and SIF 4507)
- In seven establishments, the HACCP plans were not validated to determine if they were functioning as intended. (SIF 421)
- In one establishment, the HACCP plan's record-keeping system was not adequately documenting the monitoring of CCPs and/or was not including records with actual values and observations. (SIF 7)
- Convicted felons were not prohibited from owning/operating meat establishment.

During calendar year 2001 (January 1 to November 30), Brazilian establishments exported 77,741,852 pounds of beef products to the United States. Port-of-entry rejections were for

public health (274,477 pounds) – microbiological and unsound conditions (0.35% of total imports), and transportation damage and missing shipping marks (0.03% combined), labeling defects (0.1%), miscellaneous defects (0.34%), and net weight violation (0.09%).

Brazil exports only canned corned beef, canned beef, processed beef (frozen), and cured beef to the United States. Fresh beef and pork may not be imported due to the presence of Hog Cholera, Swine Vesicular Disease, and Foot and Mouth Disease in Brazil.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Brazilian national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits to eight establishments (SIF 42, SIF 421, SIF 736, SIF 2015, SIF 2427, SIF 2979, SIF 3181, and SIF 3673). The third was conducted by on-site visits to 13 establishments (SIF 13, SIF 76, SIF 226, SIF 337, SIF 385, SIF 458, SIF 471, SIF 504, SIF 862, SIF 1651, SIF 2023, SIF 3031, and SIF 4507). The selection of the establishments for these audits was based on the examination of the port of entry (POE) rejection records and randomly. Seven establishments were selected because of their implication in misbranding of canned corned beef. This included four establishments that were involved in recall/market withdrawal of canned corned beef. Three establishments were selected because of concerns arising from the previous on-site audits; one newly approved establishment was substituted for an inactive approved establishment; one previously de-listed canned corned beef processing establishment, which had been re-listed by the GOV during audit was added the itinerary; one establishment was randomly selected. The fourth was a visit to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence of microbiological contamination with *Salmonella*.

Brazil's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the generic *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Thirteen establishments were audited. The auditor found sanitation and other conditions to be so serious in two establishments (SIF 3031 and SIF 4507) that the establishments were delisted by the Government of Brazil (GOB). The auditor found serious problems in the remaining 11establishments (SIF 13, SIF 76, SIF 226, SIF 337, SIF 385, SIF 458, SIF 471, SIF 504, SIF 862, SIF 1651, and SIF 2023). These 11 establishments were allowed to continue to operate and within 30 days be verified for full compliance by the GOB. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli*, are discussed later in this report.

As stated above, seven major concerns had been identified during the last audit of the Brazilian meat inspection system, conducted in July 2001.

During this new audit, the auditor determined that some of these major concerns had been addressed and corrected by the Ministerio da Agricultura, Pecuaria e Abastecimento (MAPA), Secretaria de Defesa Agropecuaria (SDA), Departamento de Inspecao de Produtos de Origem Animal (DIPOA). However, the following deficiencies identified in the July 2001 audit had not been addressed and corrected:

- The continuing problems with periodic supervisory reviews of certified establishments. *Repeat deficiency in all the establishments from last audit.*

- In eight establishments, the final review of all documentation associated with the production of the product prior to shipping was not done. *Repeat deficiency in two establishments from last audit and one establishment was not audited.*

- In seven establishments, the critical limits that were set were not measurable. *Repeat deficiency in all the establishments from last audit except corrected in one establishment.*

- In two establishments, the HACCP plan did not adequately address the corrective actions to be followed in response to deviations from critical limits. *Repeat deficiency in one establishment from last audit.*

- In one establishment, the HACCP plan was not validated to determine that it was functioning as intended. *Repeat deficiency from last audit.*

- In one establishment, the HACCP plan's record-keeping system was not adequately documenting the monitoring of CCPs and/or was not including records with actual values and observations. *This establishment was not audited.*

- ♦ Convicted felons were not prohibited from owning/operating meat establishment. *No additional information provided by the GOB officials.*

During this new audit, the following deficiencies were found:

1. Instances of actual product contamination and instances of the potential for direct product contamination.
2. Less than monthly supervisory reviews of 11 certified establishments and no monthly supervisory reviews in two establishments.
3. The continuing problems with the implementation and maintenance of SSOP in certified establishments.
4. The continuing problems with implementation and maintenance of HACCP systems in all certified establishments.
5. The exemption requirement from the species verification testing was not met in one establishment.
6. Deficiencies in the approved private laboratories for the testing of *Salmonella* concerning the laboratories' quality assurance programs.
7. Deficiencies in the residue Laboratorio Regional de Apoio Animal (LARA/MG) in Porto Alegre concerning the laboratory's quality assurance programs. In the other residue Laboratorio Regional de Apoio Animal (LARA/MG) in Pedro Leopoldo, mercury testing was not included in the trace element testing program.
8. The lack of inspectional control of devices (brands and including signature verification seals) requiring security and maintenance of inventory records.
9. Inadequate pest control prevention programs.
10. The GOB meat inspectors were reconditioning the dropped meat instead of inspecting and verifying the adequacy and effectiveness of handling and reconditioning of dropped meat in a sanitary manner by the establishment personnel.

Details are provided in the Slaughter/ Processing Controls and Laboratory Audits sections later in this report.

Entrance Meeting

On January 9, 2002, an entrance meeting was held at the Ministerio da Agricultura, Pecuaria e Abastecimento (MAPA), Secretaria de Defesa Agropecuaria (SDA), Departamento de Inspecao de Produtos de Origem Animal (DIPOA) in Brasilia. The Brazilian government participants were Dr. Marcelo Vieira Mazzini, Chefe da Divisao de Controle do Comercio Internacional (DCI) and Dr. Andreia Garcia de Oliveira Galvao, Medico Veterinario, (DCI). The United States government participants were Ms. Kimberly L. Svec, Agricultural Attaché, American Embassy, Brasilia; Mr. Joao Faustino Silva, Agricultural Specialist, American Embassy, Brasilia; and Dr. Faizur R. Choudry, International Audit Staff Officer, Technical Service Center (TSC), Food Safety and Inspection Service (FSIS).

Topics of discussion included the following:

- Welcome by Dr. Marcelo Vieira Mazzini, Chefe da Divisao de Controle do Comercio Internacional (DCI), and explanation of the Brazilian meat inspection system.
- Discussion of the previous audit report.
- The audit itinerary and travel arrangements.
- Training programs for veterinary meat inspection officials for pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- The auditor provided: a) copy of the current Quarterly Regulatory and Enforcement Report; b) FSIS Directive 6420.1, Livestock Post-mortem Inspection Activities-enforcing the zero tolerances for fecal material, ingesta, and milk; c) FSIS Notice, Reassessment of Listeria Monocytogenes contamination of Ready-to-Eat Products (RTE); and d) FSIS Notice-12-98, Notification to Establishments of Intended Enforcement Actions.

Headquarters Audit

There had been no changes in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Brazil's inspection system in July 2001.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents pertaining to the eight establishments listed for records review. This records review was conducted at the headquarters of the inspection service. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors.
- Label approval records such as generic labels.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Export product inspection and control including export certificates.
- Enforcement records including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding,

suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

The following concerns arose as a result the examination of these documents:

- In one establishment, the SSOP procedure did not identify the individual responsible for implementing and maintaining the activities.

- In one establishment, the records for SSOP pre-operational and operational sanitation and any corrective action taken were not being adequately maintained.

- In three establishments, the flow chart did not describe the process steps and product flow adequately.

- In seven establishments, the HACCP plan did not adequately conduct a hazard analysis that included food safety hazards likely to occur. *Repeat deficiency in one establishment from last audit.*

- In four establishments, the HACCP plan did not adequately specify critical limits for each CCP, and the monitoring frequency with which these procedures would be performed. *Repeat deficiency in one establishment from last audit.*

- In four establishments, the HACCP plan did not adequately address the corrective actions to be followed in response to deviations from critical limits.

- In seven establishments, the HACCP plans were not validated to determine if they were functioning as intended. *Repeat deficiency in one establishment from last audit.*

- In seven establishments, the HACCP plans did not adequately state the procedures that the establishment would use to verify that the plan was being effectively implemented and the frequencies with which these procedures would be performed. The on-going verification activities of the HACCP programs were not performed adequately by establishment personnel.

- In one establishment, the HACCP plan's record-keeping system was not adequately documenting the monitoring of CCPs and/or was not including records with actual values and observations.

- In six establishments, the final review of all documentation associated with the production of the product prior to shipping was not done. *Repeat deficiency in one establishment from last audit.*

- In seven establishments, the monthly supervisory visits were not performed. Only two to four internal reviews were conducted per year by the state supervisors. In one establishment, no monthly supervisory visit was performed in a year.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Brazil as eligible to export meat products to the United States were full-time DIPOA employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Twenty-nine establishments were certified to export meat products to the United States at the time this audit was conducted. Thirteen establishments (SIF 13, SIF 76, SIF 226, SIF 337, SIF 385, SIF 458, SIF 471, SIF 504, SIF 862, SIF 1651, SIF 2023, SIF 3031, and SIF 4507) were visited for on-site audits.

Two establishments (SIF 3031 and SIF 4507) were found to be unacceptable because of critical sanitation problems, findings of direct product contamination, and inadequate control of flies in the slaughter room. These establishments were delisted by the GOB. The auditor found serious problems in the remaining 11 establishments (SIF 13, SIF 76, SIF 226, SIF 337, SIF 385, SIF 458, SIF 471, SIF 504, SIF 862, SIF 1651, and SIF 2023). These 11 establishments were allowed to continue to operate and within 30 days be verified for full compliance by the GOB officials.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved, and private laboratories; intra-laboratory quality assurance procedures, including sample handling; and methodology.

The Laboratorio Regional de Apoio Animal (LARA) in Pedro Leopoldo was audited on January 16, 2002. Except as noted below, effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done. The check sample program did meet FSIS requirements.

The Laboratorio Regional de Apoio Animal (LARA/MG) in Porto Alegre was audited on January 21, 2002. This is also a reference laboratory for microbiology for the private approved laboratories. Except as noted below, effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done. The check sample program did meet FSIS requirements.

The laboratory has responsibilities in the residue testing program as well as the *E. coli* and *Salmonella* testing programs. This laboratory is providing check samples for *E. coli* and *Salmonella* testing for quality assurance programs to private approved laboratories.

The following was observed:

- Mercury testing was not included in the trace element testing program in Pedro Leopoldo Laboratory.

- Standards book for chlorinated hydrocarbons (CHC), polychlorinated biphenyls (PCBs), trace elements (TE), and chloramphenicol was not properly maintained for quality assurance program, such as: solutions prepared by the analyst were not signed and verified by the supervisor before the solutions were used; and pages were not serially numbered in Porto Alegre laboratory.

Establishment Operations by Establishment Number

The following operations were being conducted in the 13 establishments:

Beef slaughter and boning – four establishments (SIF 504, SIF 862, SIF 1651, and SIF 4507)
Beef slaughter, boning, canning, and cooked frozen beef – four establishments (SIF 337, SIF 385, SIF 458, and SIF 3031)
Dried beef extract in powder form and dairy products – one establishment (SIF 471)
Cooked frozen and dried beef (Jerky) – one establishment (SIF 13)
Canned corned beef – two establishments (SIF 226 and SIF 2023)
Canned corned beef, meat patties, and sausages – one establishment (SIF 76)

SANITATION CONTROLS

Based on the on-site audits of establishments, Brazil's inspection system had controls in place for water potability records; chlorination procedures; back-siphonage prevention; separation of operations; temperature control; work space; ventilation; ante-mortem facilities; welfare facilities; and outside premises.

Sanitation Standard Operating Procedure (SSOP)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs in the 13 establishments were found to meet the basic FSIS regulatory requirements with the following deficiencies:

- In three establishments, the written SSOP procedure did not address pre-operational sanitation.
- In one establishment, the written SSOP did not address operational sanitation.

- In one establishment, the written SSOP pre-operational procedures did not address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.

- In one establishment, the written SSOP procedure did not indicate the frequency of the pre-operational task.

- In three establishments, the SSOP procedure did not identify the individual responsible for implementing and maintaining the activities.

- In five establishments, the records for SSOP pre-operational and operational sanitation and any corrective action taken were not being adequately maintained.

- In three establishments, the daily pre-operational and/or operational sanitation SSOP deficiencies were not identified by the establishment personnel.

- In six establishments, the daily pre-operational and/or operational sanitation deficiencies were not identified and any preventive measures taken were not documented by the GOB inspection officials.

- In one establishment, the daily pre-operational sanitation was not monitored by the establishment officials to verify the adequacy and effectiveness of the sanitation SSOPs since July 2001.

Cross-Contamination: Actual product contamination and the potential for product contamination was found in all thirteen establishments audited. In some establishments, but not all, GOB officials took appropriate corrective actions. Specific findings for each establishment audited on-site can be found in Attachment F.

Examples of findings of actual product contamination include:

- In four establishments, dripping condensate from overhead exhaust tube pipe, refrigeration units, rails, beams, pipes, ducts, and ceilings, that were not cleaned/sanitized daily, was falling onto cooked ground beef, beef carcasses, packaged edible product, plastic tubes for cooked and frozen beef and containers for edible product, employees' scabbards and aprons in the coolers, offal room, at the entrance to corridor from the slaughter room, raw canned corned beef storage room, cooking room, raw cooked and frozen room, and employees' equipment and aprons cleaning room. Establishment officials retained the product, stopped the operation and took corrective action. In one of these establishments, neither establishment nor GOB inspection officials took corrective actions. In another establishment, the

corrective actions were inadequate and ineffective. *Repeat deficiency in one establishment from last audit.*

- In two establishments, the sanitizer was not maintained at the required temperature (82°C) at the de-horning station in the slaughter room and in the raw cooked and frozen room. In these two establishments, the sanitizing facility for knives was designed in such a way that it was not possible to sanitize knives completely and effectively. *Corrected immediately.*
- In one establishment, de-horning equipment was not sanitized between use on each carcass in the slaughter room. *Corrected immediately.*

- In one establishment, the automatic viscera conveyor was observed with blood, fat, pieces of meat, and hair after washing/sanitizing in the slaughter room. *Establishment officials took corrective action immediately.*

- In four establishments, exposed edible product was contacting platforms and employees' boots, dirty frame of conveyor, dirty racks and a dirty hose at the carcass splitting saw, in the boning room, slaughter room, carcass trimming station, cooking room and offal freezer. *Establishment officials ordered correction.*

- In two establishments, insanitary equipment was directly contacting edible product in the boning room, meat grinding room, and offal freezer. For example, employees' scabbards and racks for edible offal were found with dirt, fat, black discoloration, dried blood, and pieces of meat; working tables were observed with rolling edges and seams at the junctions of tables that were not sealed completely, and one conveyor belt for edible product was worn and deteriorated. *Establishment officials took corrective action temporarily and proposed permanent preventive measures to GOB officials.*

- In three establishments, water was dripping from employees' working platform onto exposed forefeet of carcasses, employees' clothes and equipment, automatic viscera conveyor after washing/sanitizing at the eviscerating platform, and hindquarter-skinning platform. *Establishment officials took corrective action temporarily and proposed permanent preventive measures to GOB officials.*

Examples of findings of <u>potential</u> cross-contamination of product include:

- In one establishment, overhead pipes in the surge room were observed with accumulation of dirt and product residue. *Establishment officials ordered correction.*

- In one establishment, several doors between boning and processing rooms had plastic strip curtains in direct contact with the floor that had a potential to contaminate employees' garments and edible product when passing through the doors. *Establishment officials corrected immediately.*

- In two establishments, gaps at the bottoms of all windows and numerous holes in screen windows in the potable water storage tank were not sealed properly to prevent the entrance of rainwater, dust, and other vermin. In one of these establishments, dust, ants, and a few vermin were observed inside the potable water storage tank. *In one establishment, officials took appropriate corrective action immediately and in the other establishment, officials ordered correction.*

- In one establishment, a hand-washing facility was too close to carcasses, creating the potential for splash contamination from dirty water during washing hands at the head removal station. In the same establishment, water was overflowing from the sanitizer onto the floor, creating the potential for dirty water splashing onto beef heads and employees' garments.

Personal Hygiene and Practices: In the area of personal hygiene and practices, the following deficiencies were noted:

- In two establishments, employees were not observing good hygienic work habits to prevent direct product contamination such as: the unclean electrical cable of an employee's wizzard knife was contacting the skinned leg area of a carcass; another employee was observed handling edible product while wearing dirty mesh gloves which were kept in the sink during washing hands and were not sanitized; also the mesh gloves were not covered with rubber gloves to prevent cross contamination at the head separation station in the slaughter room. In another establishment, an employee was observed picking up pieces of meat from the floor and, without washing his hands, handling edible product in the meat cooking room. Two employee were observed unwrapping frozen meat and allowing the dirty outside of wrapping material to contact the table and exposed meat in the meat grinding and cooking room. *Establishment officials took corrective action immediately.*

- In one establishment, receptacles for waste paper were not foot-operated at the hand washing stations. *Establishment officials ordered correction.*

Product Handling and Storage: In the area of product handling and storage, the following deficiencies were noted.

- In one establishment, numerous carcasses were observed with rail dust in the carcass cooler and, in same establishment, one hind quarter out of four was observed with hair, rail dust, dirt, and grease after pre-boning trim in the boning room. *Establishment officials took corrected action immediately.*

- In 10 establishments, product that contacted the floor (dropped meat) was not being reconditioned by the establishment personnel. The GOB meat inspectors were reconditioning the dropped meat instead of inspecting and verifying the adequacy and effectiveness of handling and reconditioning of dropped meat in a sanitary manner by

the establishment personnel. In one of these establishments, there was no facility to wash and sanitize the table after reconditioning dropped meat in the boning room.

- In 12 establishments, pest control prevention was inadequate. For example, in one establishment, the dry storage room for packaging materials had numerous holes through the walls and at the junction of walls and ceilings to the outside. The packaging material was not stored on racks that were high enough and away from walls to monitor pest control and sanitation programs and dust, dirt, cobwebs, and dead insects were observed in the room. Cartons were being stored directly on the floor. In the same establishment, in the can storage room, numerous holes were observed through the walls and at the junction of walls and ceilings to the outside and gaps at the bottoms and sides of four doors were not sealed properly to prevent the entry of rodents and other vermin. Dust, dirt, cobwebs, and dead insects were observed. Evidence of rodent infestation was observed on October 2, 2001 and in December 2001, in the employees' restaurant and incubation room by the outside pest control company, during their routine monitoring program. Rodenticides were replaced in the bait boxes but no other effort was made to take corrective/preventive measures either by the pest control company or establishment personnel/GOB meat inspection officials. In another establishment, the dry storage room for packaging materials was observed with dripping condensation on a wall, insects and also the packaging material was not stored on racks that were high enough and away from walls to monitor pest control and sanitation programs. Numerous holes at the junction of walls and ceilings to outside and gaps at the sides of the door in the dry storage room were not sealed properly to prevent the entrance of rodents and other vermin. Dead insects were observed in this room.

  In six establishments, flies were observed in the slaughter and canning rooms. In seven establishments, doors in the dry storage room, slaughter room, boning room, shipping room, can storage and labeling rooms, processing room, edible product storage room, offal room, inedible room were not sealed properly to prevent the entry of rodents and other vermin. In another establishment, the dry storage room for packaging materials was divided into two rooms and one belongs to another company. The middle wall between these two rooms was partially completed and numerous holes at the junction of walls and ceilings to the outside were not sealed properly to prevent the entrance of rodents and other vermin. *In all the establishments officials ordered correction.*

Establishment Facilities: In the area of maintenance of establishment facilities, the following deficiencies were noted:

- In five establishments, light at the carcass, viscera, head, and retained carcass postmortem inspection stations and beef head washing cabinet was inadequate. *Establishment officials ordered correction.*

- ♦ In one establishment, flaking paint was observed on walls in one freezer and broken coving in numerous places in another freezer. *Establishment officials ordered correction.*

ANIMAL DISEASE CONTROLS

Brazil's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

RESIDUE CONTROLS

Brazil's National Residue Testing Plan for 2002 was being followed, and was on schedule. The Brazilian inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals

SLAUGHTER/PROCESSING CONTROLS

The fourth of the five risk areas that the auditor looks at is Slaughter/Processing Controls. The controls include the following areas: adequate animal identification; ante-mortem inspection procedures; ante-mortem disposition; humane slaughter; post-mortem inspection procedures; post-mortem dispositions; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products. The controls also include the implementation of HACCP systems in all establishments and a generic *E. coli* testing program in slaughter establishments. Deficiencies are discussed below.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a HACCP system. Each of these systems was evaluated according to the criteria employed in the U.S domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were reviewed during the on-site audits of twelve establishments. The auditors found the following deviations from FSIS' regulatory requirements:

- In nine establishments, the HACCP plan flow chart did not adequately describe the process steps and product flow.

- In 10 establishments, the HACCP plan did not adequately conduct a hazard analysis.

- In 11 establishments, the HACCP plan did not adequately specify critical limits for each CCP and the frequency with which these procedures would be performed. *Repeat deficiency in four establishments from last audit.*

- In nine establishments, the HACCP plan did not adequately address the corrective actions to be followed in response to deviations from critical limits. *Repeat deficiency in one establishment from last audit.*

- In 12 establishments, the HACCP plan was not validated to determine if it was functioning as intended.

- In 11 establishments, the HACCP plan did not adequately state the procedures that the establishment would use to verify that the plan was being effectively implemented and the frequencies with which these procedures would be performed. The on-going verification activities of the HACCP program were not adequately performed by the establishment personnel. *Repeat deficiency in one establishment from last audit*

- In eight establishments, the HACCP plan's record keeping system was not adequately documenting the monitoring of CCPs.

- In all 13 establishments, the on-going verification activities of the HACCP program were not adequately performed by the GOB meat inspection officials.

- In three establishments, the final review of all documentation associated with the
- production of the product prior to shipping was not done. *Repeat deficiency in one establishment from last audit.*

All the establishments producing canned corned beef (SIF 76, SIF 226, SIF 337, SIF 385, SIF 458, SIF 2023, and SIF 3031) were visited for on-site audits. This included the four establishments that were involved in recall/market withdrawal of canned corned beef. The GOB meat inspection system and each establishment demonstrated control over the identification and segregation of the products during the production process. During this audit, no unapproved and unidentified raw product was observed. The implementation of a new identification system of raw product from receiving to shipping was in compliance. In addition, establishments were not using cheek meat, head meat, and hearts in canned corned beef.

Testing for Generic *E. coli*

Brazil has adopted the FSIS regulatory requirements for *E. coli* testing.

Eight out of the 13 establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the

criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The following deficiency was noted:

- In one establishment, the procedure did not designate the employee(s) responsible for collecting the samples.

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements

Additionally, establishments had adequate controls in place to prevent meat products intended for Brazilian domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

Except as noted below, the GOB inspection system controls [ante-and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, the importation of only eligible livestock from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat products from other counties for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

Eight out of the 13 establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Equivalence Determination

Brazil has adopted the FSIS regulatory requirements for *Salmonella* testing with exception of the following equivalent measures.

1. SAMPLE COLLECTOR: Establishment takes samples.

- Brazil has a clearly written sampling plan with instructions for sample collection and processing that will be universally followed. The plan is outlined in a document titled" Circular 271/97/DCI/DIPOA
- Brazil has a means of ensuring that establishment sample collection activities are appropriate and laboratory performance is acceptable. Samples are taken under the direct supervision of a government inspector. Private laboratories are authorized by the government of Brazil. Laboratories are audited twice a year by the government. Check samples are provided several times a year to check the continuing effectiveness of the laboratory results. Test results are provided directly to the government inspector at the establishment.
- Brazil uses the test results to monitor establishment performance over time.
- Brazil takes immediate action any time an establishment fails to meet a *Salmonella* performance standard

2. LABORATORIES: Private Laboratories

- Private laboratories are authorized by the government. Laboratories are subjected to a thorough review before authorization is granted. Laboratories are audited twice a year by the government. Check samples are provided several times a year to check the continuing effectiveness of the laboratory results.

- The laboratory has properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities. Test results are provided directly to the local inspection service.

3. ENFORCEMENT STRATEGY.

- Brazil suspends an establishment from export to the U.S. the first time an establishment fails to meet a *Salmonella* performance standard.
- In addition to corrective actions, the establishment reassesses its HACCP plan and a second set of samples is collected. If the establishment fails to meet the performance standard on the second sample set, then the HACCP plan is audited by the Brazilian inspection service and another sample set is collected.
- If the establishment fails to meet the performance standard on the third sample set, then the establishment is suspended from domestic production. The establishment cannot be re-certified for export until it can meet the performance standard.

The following deficiencies were noted:

- Laboratories were not audited twice a year by the government.

- Check samples were not provided several times a year to check the continuing effectiveness of the laboratory results. Check samples were provided only two times a year.

Species Verification Testing

At the time of this audit, Brazil was exempt from the species verification-testing requirement, having advised FSIS in writing that the following five conditions were being met:

1. Carcasses and products are transported between establishments in devices which are sealed with a tamper-detectable inspection seal by the Inspection Service at the originating establishment and broken by the Inspection Service at the receiving establishment.
2. Brands and sealing devices used by the Inspection Service to identify and seal product are kept under Inspection Service security.
3. Establishments are under continuous Inspection Service supervision while operating. No operations may take place without Inspection Service supervision.
4. Only one species of livestock or meat is allowed in the slaughter or processing areas at one time.
5. Product must be exported to the United States in a cargo container sealed by the Inspection Service.

During the audit, the auditor verified that these conditions continued to be met except in one establishment.

- More than one species of meat is allowed in the processing areas at one time such as beef, pork, and poultry (SIF 76).

Monthly Reviews

These monthly reviews were being performed, as required in all 13 establishments; in 11 establishments, one to six internal reviews were conducted per year by the Brazilian equivalent to Circuit Supervisors while in two other establishments, no monthly supervisory visits had been performed. All officials were veterinarians with many years of experience. Dr. Marcello Mazzini, Chief of DCI/DIPOA was in charge of the slaughter and processing establishments.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were not always announced in advance and were conducted, at times by individuals and at other times by a team of reviewers. For U.S. certified establishments, these reviews were not on a monthly basis. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the central DIPOA offices in Brasilia.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, a team is empowered to conduct an in-depth review, and the results are reported to Dr. Marcello Mazzini, Chief of DCI/DIPOA for evaluation; they formulate a plan for corrective actions and preventive measures.

Enforcement Activities

- In six establishments, inspection devices (brands) were not adequately kept under inspectional control and the inventory of inspection devices (brands) was not maintained properly by the GOB inspection officials.

Exit Meetings

An exit meeting was conducted at the Ministerio da Agricultura, Pecuaria e Abastecimento (MAPA), Secretaria de Defesa Agropecuaria (SDA), Departamento de Inspecao de Produtos de Origem Animal (DIPOA) in Brasilia, on February 6, 2002. The Brazilian government participants were Dr. Rui Eduardo Saldanha Vargas, Director do DIPOA; Dr. Carlos Eduardo Tedesco Silva, Assessora Tecnica da DCI/DIPOA; Dr. Milene Cristine Ce, Assessora Tecnica da DCI/DIPOA; and Dr. Andreia Garcia de Oliveira Galvao, Assessora Tecnica da DCI/DIPOA. The United States government participants were Ms. Kimberly L. Svec, Agricultural Attaché, American Embassy, Brasilia; Mr. Joao Faustino Silva, Agricultural Specialist, American Embassy, Brasilia; and Dr. Faizur R. Choudry, International Audit Staff Officer, Technical Service Center (TSC), Food Safety and Inspection Service (FSIS).

The auditor explained to the GOB inspection officials that this audit is only a sample of activities and therefore is subject to the risks associated with sampling. Therefore, the possibility exists that the auditor did not observe all problems during the audit. The basis of the audit was against FSIS requirements and equivalence determinations such as: Pathogen Reduction/HACCP final rule including regulations on SSOP, *E. coli* testing and *Salmonella* performance standards.

The following deficiencies were found during this audit:

1. Instances of actual product contamination and instances of the potential for direct product contamination.
2. Less than monthly supervisory reviews of 11 certified establishments and no monthly supervisory reviews in two establishments.
3. Continuing problems with the implementation and maintenance of SSOP in certified establishments.
4. Continuing problems with implementation and maintenance of HACCP systems in all certified establishments.
5. The exemption requirement from the species verification testing was not met in one establishment.
6. Deficiencies in the approved private laboratories for the testing of *Salmonella* concerning the laboratories' quality assurance programs.
7. Deficiencies in the residue Laboratorio Regional de Apoio Animal (LARA/MG) in Porto Alegre concerning the laboratory's quality assurance programs. In the other residue Laboratorio Regional de Apoio Animal (LARA/MG) in Pedro Leopoldo, mercury testing was not included in the trace element testing program.

8. Lack of inspectional control of devices (brands and including signature verification seals) requiring security and maintenance of inventory records.
9. Inadequate pest control prevention programs.
10. The GOB meat inspectors were reconditioning the dropped meat instead of inspecting and verifying the adequacy and effectiveness of handling and reconditioning of dropped meat in a sanitary manner by the establishment personnel.

Dr. Rui Eduardo Saldanha Vargas, Director do DIPOA, stated that he would take the necessary steps to ensure that corrective actions and preventive measures would be implemented, including HACCP, SSOP, and sanitation problems.

CONCLUSION

The Brazilian meat inspection system has major deficiencies, which demonstrate a lack of government oversight as evidenced by the findings presented in the report. However, a few improvements were observed in the individual establishments' HACCP and SSOP programs.

Thirteen establishments were audited. The auditor found sanitation and other conditions to be so serious in two establishments that the establishments were delisted by the GOB. The auditor found significant problems in the remaining 11 establishments. The deficiencies encountered during the on-site establishment audits, in some establishments, were adequately addressed to the auditor's satisfaction. The GOB meat inspection officials stated that they would ensure prompt compliance.

Dr. Faizur R. Choudry
International Audit Staff Officer

(signed)*Dr. Faizur R. Choudry*

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing.
D. Data collection instrument for *Salmonella* testing
E. Laboratory Audit Forms
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. identified	7. Docu-mentation done daily	8. Dated and signed
SIF13	√	√	√	√	√	√	√	√
SIF76	√	√	√	√	√	√	no	√
SIF226	√	√	√	√	√	√	√	√
SIF337	√	√	√	√	√	no	no	√
SIF385	√	√	√	√	√	√	√	√
SIF458	√	√	√	√	√	√	no	√
SIF471	√	no	no	√	√	no	no	√
SIF504	√	√	√	√	√	√	√	√
SIF862	√	no	√	√	√	√	√	√
SIF1651	√	√	√	no	√	no	√	√
SIF2023	√	√	√	√	√	√	no	√
SIF3031	√	√	√	√	√	√	√	√
SIF4507	√	√	√	√	no	√	√	√

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

SIF42	√	√	√	√	√	√	√	√
SIF421	√	√	√	√	√	no	no	√
SIF736	√	√	√	√	√	√	√	√
SIF2015	√	√	√	√	√	√	√	√
SIF2427	√	√	√	√	√	√	√	√
SIF2979	√	√	√	√	√	√	√	√
SIF3181	√	√	√	√	√	√	√	√
SIF3673	√	√	√	√	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. procedures	10.Adequate documentation	11. Dated and signed	12.Pre-shipmt. doc. review
13	√	no	√	√	√	no	√	√	no	√	√	√
76	no	no	√	√	√	no	no	no	no	√	√	√
226	no	no	√	√	√	no	no	no	no	no	√	√
337	√	no	√	√	√	no	√	no	no	no	√	√
385	no	no	√	√	√	√	no	no	no	no	√	no
458	no	no	√	√	√	no	no	no	no	no	√	√
471	no	no	√	√	√	no	no	no	no	√	√	√
504	no	√	√	√	√	√	√	no	√	no	√	√
862	no	no	√	√	√	no	no	no	no	no	√	√
1651	no	no	√	√	√	no	no	no	no	no	√	no
2023	√	√	√	√	√	no	√	no	√	√	√	√
3031	no	√	√	√	√	no	no	no	no	no	√	no
4507	√	no	√	√	√	no	no	no	no	√	√	√

No = Establishment met FSIS basic regulatory requirements of HACCP programs. The HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation.

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. procedures	10.Adequate documentation	11. Dated and signed	12.Pre-shipmt. doc. review
42	no	no	√	√	√	no	no	no	no	√	√	no
421	no	no	√	√	√	no	no	no	no	√	√	no
736	√	no	√	√	√	no	no	no	no	√	√	no
2015	√	no	√	√	√	√	√	no	no	no	√	no
2427	cold	storage										
2979	no	no	√	√	√	√	√	no	no	√	√	no
3181	√	no	√	√	√	√	√	no	no	√	√	no
3673	√	no	√	√	√	no	no	no	no	no	√	no

No = Establishment met FSIS basic regulatory requirements of HACCP programs. The HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation.

Attachment C

Data Collection Instrument for Generic E. coli Testing

Each establishment (except Est. 13, 76, 226, 471, and 2023, which were processing establishments) was evaluated to determine if the basic FSIS regulatory requirements for generic E. coli testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. Species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
13	cooked	frozen	beef							
76	canned	corned	beef							
226	canned	corned	beef							
337	√	√	√	√	√	√	√	√	√	√
385	√	√	√	√	√	√	√	√	√	√
458	√	√	√	√	√	√	√	√	√	√
471	Beef	extract								
504	√	√	√	√	√	√	√	√	√	√
862	√	no	√	√	√	√	√	√	√	√
1651	√	√	√	√	√	√	√	√	√	√
2023	canned	corned	beef							
3031	√	√	√	√	√	√	√	√	√	√
4507	√	√	√	√	√	√	√	√	√	√

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
42	√	√	√	√	√	√	√	√	√	√
421	√	√	√	√	√	√	√	√	√	√
736	canned	corned	beef							
2015	cooked	frozen	beef							
2427	Cold	Store								
2979	√	√	√	√	√	√	√	√	√	√
3181	√	√	√	√	√	√	√	√	√	√
3673	Cured	beef								

Attachment D

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
SIF13	Cooked	& frozen				
SIF76	Canned	corned beef				
SIF226	Canned	corned	beef			
SIF337	√	√	N/A	√	√	√
SIF385	Canned	Corned beef	& cooked	frozen beef		√
SIF458	Canned	Corned beef	& cooked	frozen beef		
SIF471	√	√	N/A	√	√	√
SIF504	√	√	N/A	√	√	√
SIF862	√	√	N/A	√	√	√
SIF1651	√	√	N/A	√	√	√
SIF2023	Canned	corned beef				
SIF3031	√	√	N/A	√	√	√
SIF4507	√	√	N/A	√	√	√

Documentation was also audited from the following establishments that were not visited on-site, during the centralized document audit:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
SIF42	√	√	√	√	√	√
SIF421	√	√	√	√	√	√
SIF736	Canned	Corned	beef			
SIF2015	Cooked	& frozen	beef			
SIF2427	Cold storage					
SIF2979	√	√	√	√	√	√
SIF3181	√	√	√	√	√	√
SIF3673	Cured beef					